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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health Statement of Organization, Functions, and Delegations of Authority

Part N, National Institutes of Health (NIH), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 66 FR 6617, January 22, 2001, and redesignated from Part HN as Part N at 60 FR 56605, November 9, 1995), is amended as set forth below to establish the National Center for Advancing Translational Science (NCATS), to abolish the National Center for Research Review (NCRR), and to establish organizational components within National Institute of General Medical Sciences (NIGMS), National Institute on Minority Health and Health Disparities (NIMHD) and the NIH Office of the Director (OD).

Section N-8, Organization and Functions, is amended as follows:

Immediately after the paragraph headed “Division of Program Coordination and Integration” (N 875, formerly HN 875), insert the following:

National Center for Advancing Translational Sciences (NCATS) (N 9, formerly HN 9) (1) Provides leadership for a national program to advance the discipline of translational science and catalyze the generation of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions; (2) conducts intramural research; (3) supports and coordinates research projects through research grants, contracts, and other mechanisms; (4) supports training in translational sciences; (5) collaborates with

organizations and other institutions engaged in translational research and training activities; and (6) collects and disseminates research findings and related information.

Office of the Director (OD) (N 91, formerly HN 91) (1) Develops and provides leadership for the Center's translational science programs; (2) manages and directs executive-level activities and functions; (3) provides policy guidance and overall operational coordination for the organizational units within NCATS; and (4) manages critical points of contact and related information flows to respond to external inquiries.

Division of Pre-Clinical Innovation (DPI) (N 92, formerly HN 92) (1) Plans, conducts, and supports research across the pre-clinical phases of the translational science spectrum; (2) plans, conducts, and supports research to develop new methods and technologies to enhance pre-clinical processes; (3) plans, conducts, and supports research to evaluate existing and developing approaches, technologies, and processes in the pre-clinical spectrum; (4) supports training programs relevant to pre-clinical phases of translational science; (5) allocates resources to pre-clinical extramural and intramural investigators; (6) collaborates with ICs and the scientists they support; and (7) consults with stakeholders, including patients, industry, and regulators.

Division of Clinical Innovation (DCI) (N 93, formerly HN 93) (1) Plans, conducts, and supports research across the clinical phases of the translational science spectrum; (2) plans, conducts, and supports research to develop new methods and technologies to enhance clinical processes; (3) plans, conducts, and supports research to evaluate existing and developing approaches, technologies, and processes in the clinical spectrum; (4) supports training programs relevant to clinical phases of

translational science; (5) allocates resources to clinical extramural and intramural investigators; (6) collaborates with ICs and the scientists they support; and (7) consults with stakeholders, including patients, industry, and regulators.

Executive Office (EO) (N 912, formerly HN 912) (1) Directs the administrative management and financial management operations of NCATS; (2) develops, administers, and directs NCATS' internal control processes; (3) oversees development of and administers NCATS policies and procedures for administrative, program management, and information technology activities; and (4) oversees personnel management and workforce planning.

Office of Grants Management and Scientific Review (OGMSR) (N 913, formerly, HN 913) (1) Provides advice and assistance to the Director of NCATS, NCATS Division Directors, and other NCATS officials on issues related to policy and procedures for extramural activities; (2) provides oversight and direction for scientific review and grants management activities of NCATS; (3) coordinates NCATS small business research programs and other special grants programs; (4) manages the operations of the national advisory council for NCATS; and (5) provides coordination, support, and staff services for committee management.

Office of Rare Diseases Research (ORDR) (N 914, formerly, HN 914) (1) Guides and coordinates NIH-wide activities involving research into combating and treating the broad array of rare (orphan) diseases; (2) manages the NIH Rare Diseases and Orphan Products Coordinating Committee (Trans-NIH Rare Diseases Working Group); (3) develops and maintains a centralized database on rare diseases; (4) coordinates and provides liaison with Federal and non-Federal national and international organizations

concerned with rare disease research and orphan products development; (5) advises the OD/NIH on matters relating to NIH-sponsored research activities that involve rare diseases and conditions; and (6) responds to requests for information on highly technical matters and matters of public policy relative to rare diseases and orphan products.

Office of Policy, Communications, and Strategic Alliances (OPCSA) (N 915, formerly, HN 915) (1) Provides leadership and direction to the planning, coordinating, reporting, analytical, evaluative, and legislative functions that support NCATS program development, science policy formulation, and overall program direction and decision-making activities of the NCATS executive staff; (2) advises the NCATS Director on policy matters pertaining to NCATS scientific programs; (3) communicates information about NCATS programs and accomplishments to a wide range of audiences; (4) advises the NCATS Director on effective communications strategies; (5) fosters relationships and partnerships with stakeholders; (6) assists in the development of content for internal and external web sites and audiences; (7) develops and executes a strategy for education and training for the disciplines that constitute translational science; (8) facilitates and supports partnerships with NIH OD, other ICs, patient groups, other governmental agencies, nonprofits and the private sector to achieve the goals of the Center; and (9) oversees and manages NCATS technology transfer activities including overseeing NCATS intellectual property, patent, and licensing agreement portfolios.

Section N-D, Organization and Functions, is amended as follows:

Immediately after the paragraph headed “Office of Grants Management” (N D43, formerly HN D43), insert the following:

Office of Research Training and Capacity Building (ORTCB) (N E32, formerly HN E32) (1) Plans, designs, develops and manages a diverse portfolio of training and career development programs and activities; (2) plans, develops, coordinates, supports and manages programs to expand the Nation's capacity to conduct research at institutions conducting and/or interested in minority health and health disparities research; (3) provides technical assistance to faculty, institutions, community groups and other organizations conducting and/or interested in minority health and health disparities research; and (4) provides support to improve, through construction, facilities conducting biomedical and behavioral research on minority health and health disparities.

Office of Innovation and Program Coordination (ORIPC) (N E33, formerly HN E33) (1) Plans, stimulates, develops and supports a broad extramural research program to include basic, behavioral and clinical research on minority health and health disparity conditions including research to prevent, diagnose and treat such conditions; (2) develops innovative research programs and projects for the Institute that link the biological and non-biological determinants of health; and (3) works with the Office of the Director to coordinate inter- and intra-agency programs and projects on minority health and health disparities.

Section N-R, Organization and Functions, is amended as follows:

Immediately after the paragraph headed “Division of Research Infrastructure” (N RL, formerly HN RL), insert the following:

Division of Training, Workforce Development, and Diversity (DTWDD) (N S5, formerly HN S5) (1) Serves as the focal point for the Institute's efforts to foster research training and facilitate the

development of a diverse and inclusive biomedical research workforce; (2) oversees and coordinates NIGMS policies related to diversity activities, research training programs, and workforce development efforts; (3) implements strategic plans to improve the effectiveness of NIGMS' diversity and training programs; (4) promotes biomedical research workforce diversity through innovative approaches, including programs to increase the competitiveness of faculty at institutions from states with limited NIH research support; and (5) collaborates with NIH, DHHS, and other agencies, as well as the extramural scientific community on these matters.

Division of Biomedical Technology, Bioinformatics, and Computational Biology (DBTBCB) (N S7, formerly HN S7) 1) Plans, directs, and administers a program of research grants, contracts, and other funding mechanisms to support research and research training in data management, analysis and visualization, computational modeling and analysis of systems and networks, including biostatistical analyses, as well as the development of new or improved technologies - in areas such as high performance computing, molecular imaging, structural biology and proteomics - which will be applied to advance biomedical research; (2) defines the Institute's needs for database development and applications, as well as collaborates with other NIH components and federal agencies in developing policies in this area; (3) coordinates the activities of the Biomedical Information Science and Technology Initiative (BISTI) and the trans-NIH Biomedical Information Science and Technology Initiative Committee (BISTIC) with related activities of other federal agencies, NIH institutes, and public and private entities; (4) analyzes national research efforts directed toward the study of the above and makes recommendations to assist the National Advisory General Medical Sciences Council or other advisory committees or appointed groups to (a) participate in decisions about new or continuing areas of program emphasis, or (b) determine the relative scientific merit of applications for grant support; (5)

maintains surveillance over new research developments and identifies the need for research in the areas of computational analysis of biological systems at the cellular, subcellular, physiological and population systems levels, as well as innovative technologies and instrumentation for biomedical research which could be used by a wide range of biomedical or clinical researchers and not limited to a specific organ or disease; and (6) provides information to third parties such as universities, other centers of biomedical research, and professional and lay organizations about research needs and requirements of the Division.

Section N-AW, Organization and Functions, is amended as follows:

Immediately after the paragraph headed “Office of Grants Management” (N AV5, formerly HN AV5), insert the following:

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

(N AW, formerly HN AW) (1) Identifies, reports on, and provides support for research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between two or more Institutes and Centers (ICs), or would otherwise benefit from strategic coordination and planning; (2) coordinates and provides support for research and activities related to AIDS, behavioral and social sciences, women’s health, disease prevention, and dietary supplements; (3) applies resources (databases, analytic tools, and methodologies) and develops specifications for new resources in support of portfolio analyses and priority setting in scientific areas of interest across NIH; (4) engages in activities designed to ensure that NIH addresses important areas of emerging scientific opportunities and public health challenges effectively; (5) plans, conducts, coordinates, and supports program evaluations and coordinates and prepares reports required by the

Government Performance and Results Modernization Act and related performance management initiatives; (6) provides animal models, supports the identification and development of new and improved animal models for the study of human diseases, provides repositories for the storage and distribution of genetically-altered animal models, and supports specialized animal research facilities for biomedical investigators; (7) supports the development of research models; (8) supports research activities at National Primate Research Centers; (9) provides oversight for the NIH Chimpanzee Management Program (ChiMP) and provides a chimpanzee sanctuary for the lifetime care of research chimpanzees that are no longer needed for biomedical research; (10) supports the improvement of the health and well-being of laboratory animals; (11) supports the breeding of and accessibility to scarce research animals; (12) supports training and career development for veterinarians engaged in research; (13) provides access for biomedical researchers to an array of biological materials and human biospecimens; (14) provides support to improve biomedical and behavioral research facilities through construction and renovation; and (15) plans, develops, coordinates, and provides support for a science education program to improve science literacy in adults and children and to attract young people to biomedical and behavioral science careers.

Office of Research Infrastructure Programs (ORIP) (N AW9, formerly HN AW9) (1) Provides support for resource activities and research to identify, develop, characterize, and improve animal models for the study of human disease; (2) assists institutions in complying with the regulations and policies related to care and use of laboratory animals, and supports the purchase of equipment for animal resources, transgenic animal resources, and similar activities; (3) provides high-quality, disease-free animal models and specialized animal research facilities for biomedical investigators; (4) supports the development and access to a wide range of research models, including vertebrate and invertebrate

species; (5) provides access for biomedical researchers to an array of biological materials and human biospecimens; (6) supports research activities at National Primate Research Centers; (7) develops and implements policies and provides programmatic oversight for the NIH Chimpanzee Management Program (ChiMP); (8) provides a chimpanzee sanctuary for the lifetime care of chimpanzees no longer needed for biomedical research; (9) supports training and career development for veterinarians engaged in research; (10) provides repositories for the storage and distribution of genetically altered animal models; (11) supports the breeding of and accessibility to scarce research animals; (12) supports grants for the acquisition of state-of-the-art instrumentation and integrated instrument systems; (13) provides support for human tissue and organ research resources to meet the needs of biomedical researchers, including those in academia, government, and industry; (14) supports grants to expand, re-model, renovate, or alter existing research facilities or to construct new research facilities, including to improve laboratory animal facilities; and (15) coordinates science education activities at the NIH, plans, develops, and coordinates a comprehensive science education program to improve science literacy in both adults and children and to attract young people to biomedical and behavioral science careers; and develops, and supports grants designed to improve life science literacy throughout the nation through educational programs.

Division of Comparative Medicine (DCM) (N AW92, formerly, HN AW92) (1) Provides high-quality, disease-free animal models and specialized animal research facilities for biomedical investigators; (2) supports the development of and access to a wide range of research models, including vertebrate and invertebrate species; (3) provides access for biomedical researchers to an array of biological materials and human biospecimens; (4) supports research activities at National Primate Research Centers; (5) develops and implements policies and provides programmatic oversight for the NIH Chimpanzee

Management Program (ChiMP); (6) provides a chimpanzee sanctuary for the lifetime care of research chimpanzees that are no longer needed for biomedical research; (7) supports the identification and development of new and improved animal models for the study of human diseases; (8) supports improvement of the health and well-being of laboratory animals; (9) supports training and career development for veterinarians engaged in research; (10) provides repositories for the storage and distribution of genetically altered animal models; and (11) supports the breeding of and accessibility to scarce research animals.

Division of Instruments, Infrastructure Resources, and Construction (DIIRC)

(N AW93, formerly, HN AW93) (1) Supports programs to expand the Nation's capacity for the conduct of biomedical research; (2) supports grants for the acquisition of state-of-the-art instrumentation and integrated instrument systems; (3) provides support for human tissue and organ research resources to meet the needs of biomedical researchers, including those in academia, government, and industry; and (4) supports grants to expand, re-model, renovate, or alter existing research facilities or to construct new research facilities, including to improve laboratory animal facilities.

Office of Science Education (OSE) (N AW94, formerly, HN AW94) (1) Plans, develops, and coordinates a comprehensive science education program to improve science literacy in both adults and children and to attract young people to biomedical and behavioral science careers; (2) develops and directs an extensive set of education initiatives in the medical sciences targeted to students in grades K-16, educators, and the public; (3) advises NIH leadership on science education issues; (4) conducts, analyzes, and assesses research related to science education; (5) collaborates within the NIH and with public and private sector organizations to develop and coordinate science education activities; and (6)

serves as an information resource center providing access to educational materials and activities related to medical science.

DELEGATIONS OF AUTHORITY STATEMENT: All delegations and redelegations of authority to officers and employees of NIH that were in effect immediately prior to the effective date of this reorganization and are consistent with this reorganization shall continue in effect, pending further redelegation.

Dated: December 30, 2011

Francis S. Collins,

Director

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